

REMARKS

The Office Action

The Office Action Summary indicates this action is non-final, as does the PAIR Transaction History and Application Data status. Furthermore, the Office Action lacks any other indication that the Office Action is final (e.g., the boilerplate text generally found at the end of final office actions concerning the after-final filing provisions). But PAIR labels the document description as a Final Rejection in the image file wrapper. The Applicants presume the image file wrapper label is incorrect.

The Claims

Claims 1-11, 13, 14 and 31-36 are pending in the application. Claims 1-11, 13, 14 and 31-36 were rejected. Claim 7 has been canceled. Claims 1-6, 8-11, 13, 14, and 31-35 have been amended as described below. New claims 37-39 have been added. The Applicants preserve the right to pursue the canceled matter in a subsequent divisional application.

New Claims 37-39 are based upon Original claim 2 and Original claim 14. No new matter has been added.

Lack of Unity

Claims 1-11, 13, 14, and 31-36 were cited for Lack of Unity as not limited to Group 1 of the elected species. After amendment, all claims read upon the elected subject matter of Group 1. The Applicants preserve the right to pursue the canceled matter in a subsequent divisional application.

Rejections under 35 U.S.C. § 112

Claims 1, 2:

The definition of Q¹ in claims 1 and 2 were rejected as allegedly indefinite. The Applicants respectfully traverse but, nevertheless, have amended claims 1 and 2 to state, “wherein the optional substituents are independently Q¹...” the applicant submit that this amendment merely further clarifies the claim and does not change its scope.

Claims 1-11, 13, 14 and 31-36:

The preambles of claims 1-11, 13, 14, and 31-36 were rejected as allegedly being improper composition claims for failing to recite an ingredient other than the compound itself. The independent claims 1 and 2 have been amended to recite the composition as a compound of formula (I) in addition to a pharmaceutically acceptable excipient. Pharmaceutical acceptable vehicles, lubricants, binders, and diluents are included in the excipients provided in the specification on pages 42-57. The balance of the rejected claims depend from claim 1 or claim 2. No new matter has been added.

Claims 1-11, 13, 14 and 31-36:

The meanings of claims 1-11, 13, 14, and 31-36 were rejected as including the term “pseudohalo,” which the Office alleged could have several meanings, including as the title of a song by the songster Malf found on YouTube. Rather than incorporate the YouTube track as a limitation into the claims, the applicants refer to the definition of pseudohalo provided on page 18, line 8 of the specification. The definition therein states:

“As used herein, pseudohalides or pseudohalo groups are groups that behave substantially similar to halides. Such compounds can be used in the same manner and treated in the same manner as halides. Pseudohalides include, but are not limited to, cyanide, cyanate, thiocyanate, selenocyanate, trifluoromethoxy, and azide.”

With all due respect to Malf, the amended claim set has replaced the term pseudohalo with the definition from the specification. No new matter has been added.

Claims 1-11, 13, 14 and 31-36:

The definitions of R^{31} , R^{34} , R^{35} , R^{36} and R^{16} were rejected as including the allegedly undefined term “alkoalkenyl.” The term has been deleted from the claims.

Claim 14:

Claim 14 was allegedly incomplete for importing limitations (FIG 1) from the specification. The compounds shown in FIG 1 have been expressly incorporated into amended claim 14. Several compounds that are not included in the amended generic claims have been deleted. No new matter has been added.

New Claim 39 lists compounds that were canceled from Original claim 14..

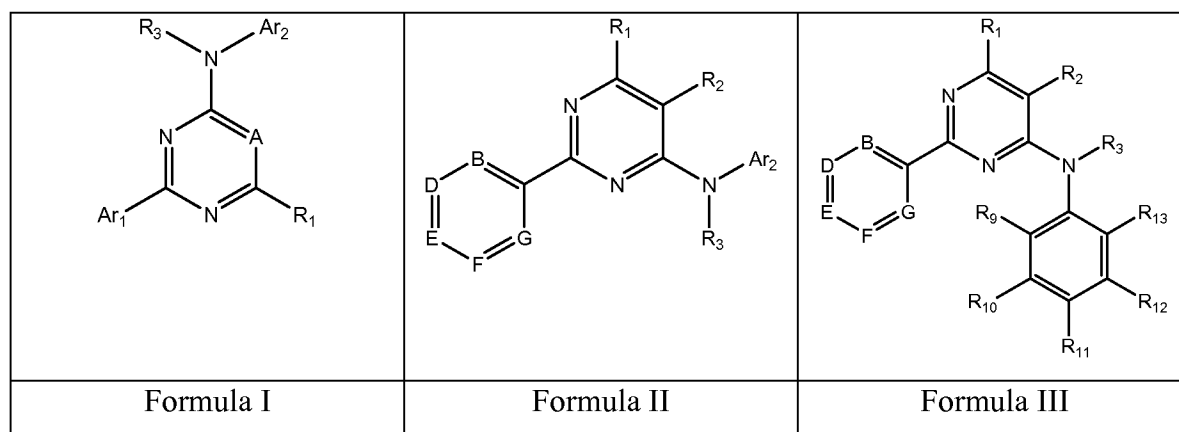
Claims 32, 34-36:

Claims 32 and 34-36 were rejected for having parenthetical phrases “i.e.,” “e.g.,” “also known as,” “such as,” and allegedly definitional phrases. The claims have been amended to remove the parenthetical and definitional phrases.

Rejections under 35 U.S.C. § 102

Cai:

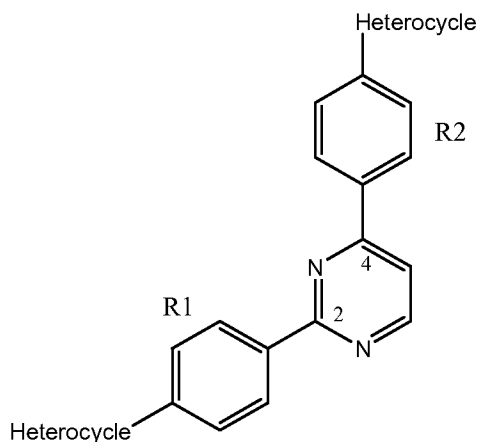
Claims 1-6, 8-11, 13, 14, 31 and 33 were rejected over Cai, et al., US 7,226,927, as allegedly being anticipated under USC § 102(a). The Cai reference describes substituted pyrimidines of the general structures of Formulas I, II and III as shown below.



The claims 1-6, 8-11, 13, 14, 31 and 33 as amended do not include anilino substituents on the pyrimidine ring. Therefore, Cai does not anticipate the amended claims.

Jiao:

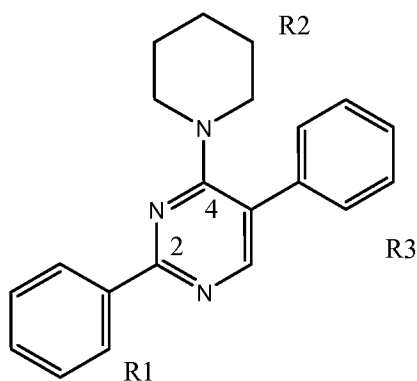
Claims 1, 11, 13, 14, and 31 were rejected under 35 USC 102(a) over Jiao, et al., US 6608066, which discloses a substituted heterocycle having the carbon backbone of the 2,4-diphenyl-pyrimidine:



The amended claims do not include 4-phenyl-pyrimidines. The reference does not anticipate the claims as amended.

Ahmed:

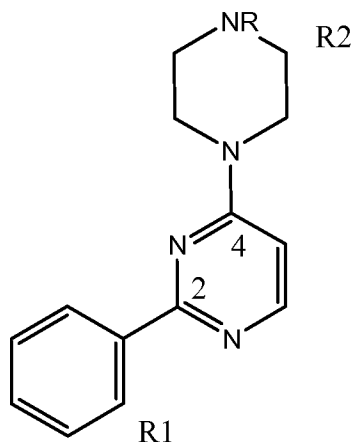
Claims 1, 11, 13, 14, and 31 were rejected under 35 USC 102(a) over Ahmad, et al, US 6887870, which discloses a compound having the following carbon backbone:



The amended claims do not encompass heterocycles at 4-pyrimidine position, nor phenyl at the 5-pyrimidine position. The reference does not anticipate the claims as amended.

Chu-Moyer:

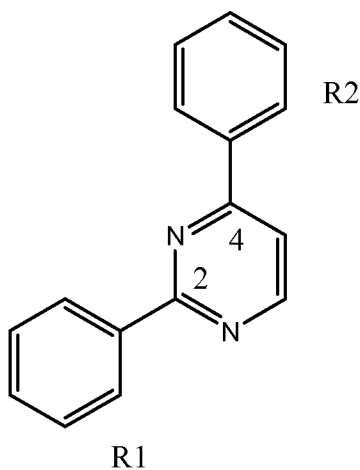
Claims 1, 11, 13, 14, and 31 were rejected under 35 USC 102(b) over, US 6414149, which discloses a compound having the following carbon backbone:



The amended claims do not encompass heterocycles at the 4-pyrimidine position. Thus the reference does not anticipate the claims as amended.

Kinoshita:

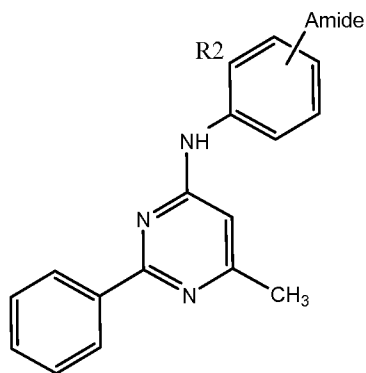
Claims 1, 11, 13, 14, and 31 were rejected under 35 USC 102(b) over Kinoshita, WO 2000041999, which discloses two compounds having the following carbon backbone:



The amended claims do not include aryl substituents at the 4-pyrimidine position. The reference does not anticipate the claims as amended.

Fauran:

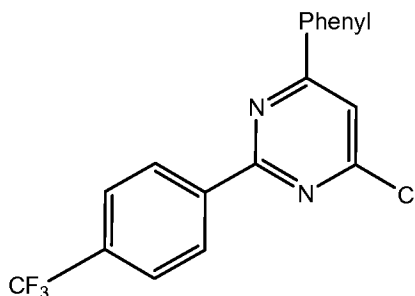
Claims 1, 11, 13, 14, and 31 were rejected under 35 USC 102(b) over Fauran, US 4041030, which discloses compounds having the following carbon backbone:



The Fauran patent does not disclose a carboxyl group on the anilino group. Thus, the reference does not anticipate the instant claims.

Murata:

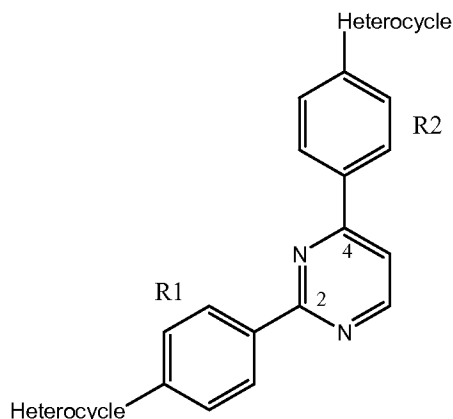
Claims 1, 11, 13, 14, 31, and 33 were rejected under 35 USC 102(b) over Murata, JP 2001139560 describing the following compound:



The amended claims do not include phenyl or aryl at the 4-pyrimidine position. The reference does not anticipate the claims as amended.

Nichols:

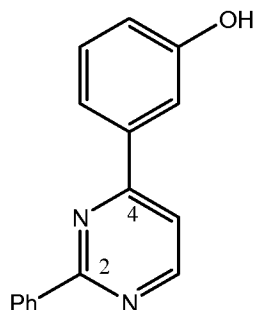
Claims 1, 11, 13, 14, and 31 were rejected under 35 USC 102(e) over Nichols, WO 2005020913, which discloses two compounds having the following backbone structure:



The amended claims do not include aryl or phenyl as a substituent at the 4-pyrimidine position, nor the heterocyclyl substituents shown. The reference does not anticipate the claims as amended.

Nunes:

Claims 1, 11, 13, 14, 31 and 33 were rejected under 102(e) over Nunes, WO 2005009443, which discloses the following compound:

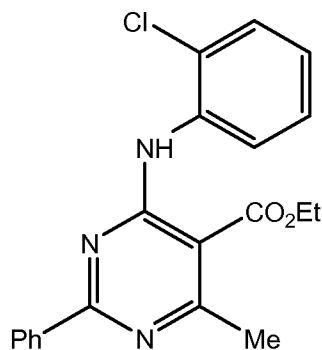


The amended claims do not include aryl or phenyl as 4-pyrimidine substituents. The reference does not anticipate the claims as amended.

Rejections under 35 U.S.C. § 103

Cieplik 1:

Claims 1-7, 11, 13, 14, and 31 stand rejected under 35 USC 103(a) over Cieplik, et al., Acta Polon. Pharma. (1994), 51(1), 59-62, which describes compositions of compounds similar to the following structure:

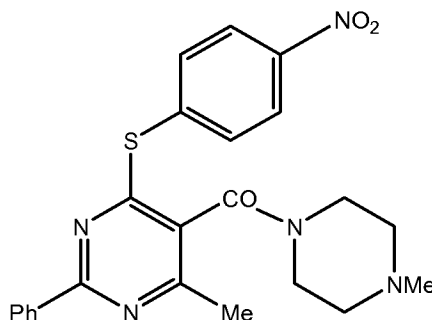


The reference was cited as allegedly creating a prima facie case of obviousness. As noted above, claims 1-7, 11, 13, 14 and 31 have been amended to remove anilino at the 4-pyrimidine position.

New claims 37-39 allow anilino substituents containing a carboxyl group substitution. The reference compounds do not contain a carboxyl substitution on the anilino ring, nor is the carboxylate shown at the 5-pyrimidine position in an isomeric or homolog relationship with the allowable substituents in the amended claims. Accordingly, the applicants respectfully submit that the pending claims are not obvious over this reference.

Ohkubo:

Claims 1-6, 8, 10, 11, 13, 14, and 31 stand rejected under 35 USC 103(a) over Ohkubo, Chem. & Pharm. Bull. (1994), 42(6), 1279-85, which describes compositions of compounds having the following backbone structure:

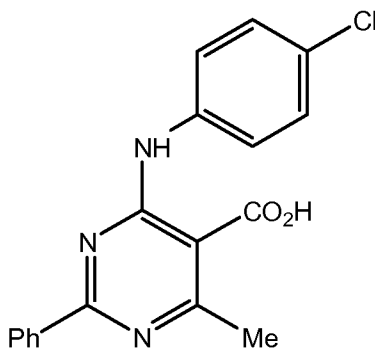


The reference allegedly made the claims obvious because the structure shown was an isomer of a homolog of the Original claims. While the art cited by the Examiner states that obviousness can be found by an isomer or that obviousness can be found in the instance of a homolog, the sources cited by the Examiner do not support a finding of obviousness created by an “isomer of a homolog” as in this instance.

Nevertheless, the Applicants have amended claims to remove alkylamides from the definition of Q¹, R³ and R⁴. The Ohkubo compound does not contain a carboxylic acid substitution on the phenylthio ring, nor is the piperazine-amide group in an isomeric or homolog relationship with the allowable substituents in the amended claims. Accordingly, the applicants respectfully submit that the pending claims are not obvious over this reference.

Machon 1:

Claims 1-7, 11, 13, 14, and 31 stand rejected under 35 USC 103(a) over Machon, et al., PL 130888, which describes compositions of the following compound:

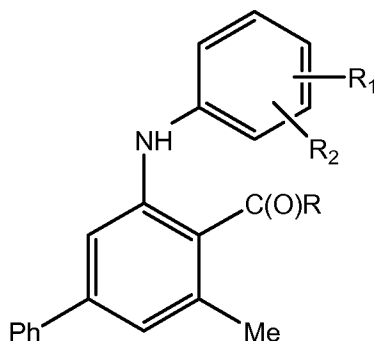


As noted above, claims 1-7, 11, 13, 14 and 31 have been amended to remove anilino at the 4-pyrimidine position.

New claims 37-39 allow anilino substituents containing a carboxyl group substitution. The above compound does not contain a carboxylic acid substitution on the anilino ring, nor is the pyrimidine carboxylic acid functional group in an isomeric or homolog relationship with allowable substituents of the amended claims. Accordingly, the applicants respectfully submit that the pending application is not prima facie obvious over the reference.

Machon 2:

Claims 1-7, 11, 13, 14, and 31 stand rejected under 35 USC 103(a) over Machon, et al., Eur. J. Med. Chem. (1984), 19(4), 359-63, which describes compositions of the following general structure:

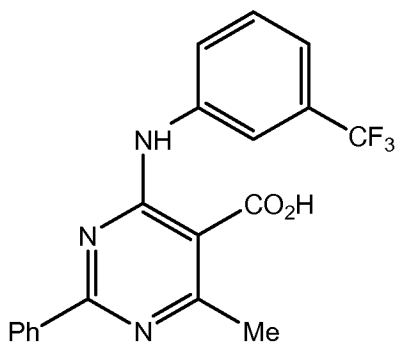


The reference was cited as allegedly creating a prima facie case of obviousness against the claims before amendment. As noted above, claims 1-7, 11, 13, 14 and 31 have been amended to remove anilino at the 4-pyrimidine position.

New claims 37-39 allow anilino substituents containing a carboxyl group substitution. Because the Machon compounds do not contain a carboxylic acid substitution on the anilino ring, and the pyrimidine carboxyl substituent is not an isomer nor in a homolog relationship with the substituents in the amended claims. The pending application is not prima facie obvious over this reference.

Kim:

Claims 1-7, 11, 13, 14, 31 and 33 stand rejected under 35 USC 103(a) over Kim, US 3860596, which describes compositions exemplified by the following compound:



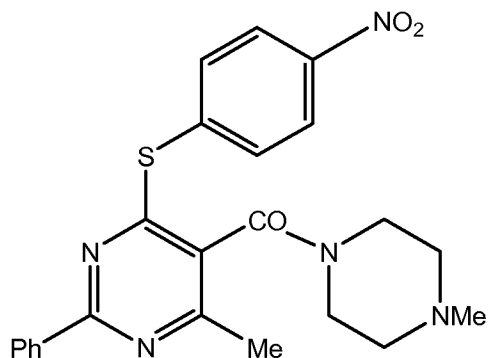
As noted above, claims 1-7, 11, 13, 14 and 31 have been amended to remove anilino at the 4-pyrimidine position.

New claims 37-39 allow anilino substituents containing a carboxyl group substitution. The Kim compounds do not contain a carboxylic acid substitution on the anilino ring, nor is the carboxyl group at the 5-pyrimidine position in an isomeric or homolog relationship with the

substituents in the amended claims. The pending claims are not prima facie obvious over this reference.

Takatani:

Claims 1-8, 10, 11, 13, 14, and 31 stand rejected under 35 USC [102(b)] 103(a) over Takatani, et al., JP 63107966, which describes compositions of compounds exemplified by the following structure:

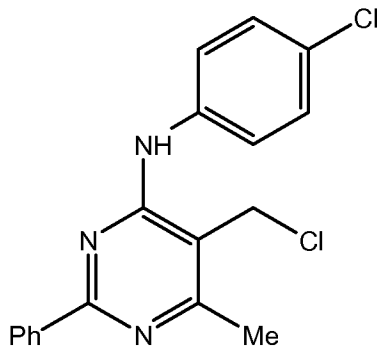


The reference allegedly made the claims obvious because the structure shown was an ‘isomer of a homolog’ of the Original claims. While the references cited by the Examiner state that obviousness can be found by an isomer or that obviousness can be found in the instance of a homolog, the sources cited do not support finding obviousness created by an isomer of a homolog as in this instance.

Nevertheless, the claims have been amended to remove alkylamides from the definition of Q¹, R³ and R⁴. The reference compounds do not contain a carboxyl substitution on the thiophenyl ring, nor is the reference’s amide functionality in an isomeric or homolog relationship with allowable substituents in the amended claims. The pending claims are not prima facie obvious over this reference.

Cieplik 2:

Claims 1-7, 11, 13, 14, and 31 stand rejected under 35 USC 103(a) over Cieplik, et al., Acta Polon. Pharm. (2003), 60(6), 487-492, that describes compositions of the following compound:

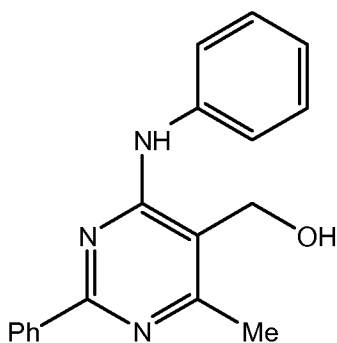


The reference was cited as allegedly creating a prima facie case of obviousness against the claims before amendment. As noted above, claims 1-7, 11, 13, 14 and 31 have been amended to remove anilino at the 4-pyrimidine position.

New claims 37-39 allow anilino substituents containing a carboxyl group substitution. The Ceiplik compound does not contain a carboxyl substitution on the anilino ring, further, the R³ and R⁴ groups in neither an isomer nor in a homolog relationship with the substituents in the amended claims. The pending application is not prima facie obvious over this reference.

Ceiplik 3:

Claims 1-7, 11, 13, 14, and 31 stand rejected under 35 USC 103(a) over Cieplik, et al., Bollet. Chim. Farm. (2003), 142(4), 146-150, which describes compositions of the following compound:



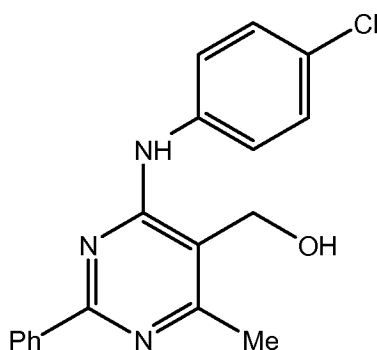
The reference was cited as allegedly creating a prima facie case of obviousness against the claims before amendment. As noted above, claims 1-7, 11, 13, 14 and 31 have been amended to remove anilino at the 4-pyrimidine position.

New claims 37-39 allow anilino substituents containing a carboxyl group substitution. The Ceiplik compound does not contain a carboxyl substitution on the anilino ring, further, the

R³ and R⁴ groups are neither in an isomeric nor in a homolog relationship with the substituents in the amended claims. The pending application is not prima facie obvious over this reference.

Ceiplik 4:

Claims 1-7, 11, 13, 14, and 31 stand rejected under 35 USC103(a) over Cieplik, et al., PL 194083, which describes compositions of the following compound:

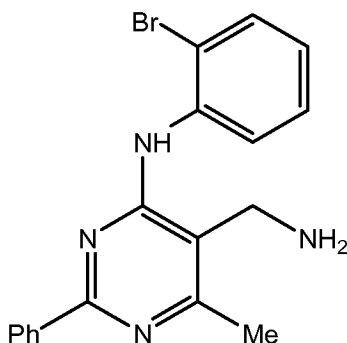


The reference was cited as allegedly creating a prima facie case of obviousness against the claims before amendment. As noted above, claims 1-7, 11, 13, 14 and 31 have been amended to remove anilino at the 4-pyrimidine position.

New claims 37-39 allow anilino substituents containing a carboxyl group substitution. The compound does not contain a carboxylic acid substitution on the anilino ring. Further, the R³ and R⁴ groups are not in an isomeric nor in a homolog relationship with the substituents in the amended claims. The pending application is not prima facie obvious over this reference by Cieplik.

Ceiplik 5:

Claims 1-7, 11, 13, 14, and 31 stand rejected under 35 USC103(a) over Cieplik, Sci. Pharm. (2002), 70(3), 245-252, which describes compositions of the following compound:

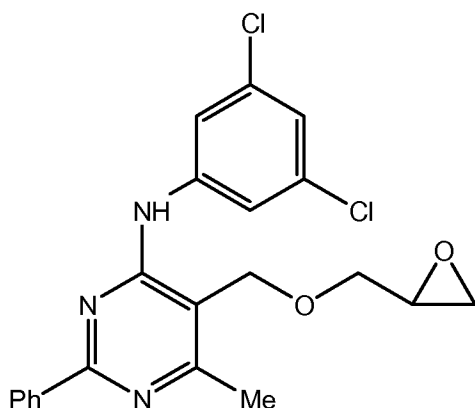


The reference was cited as allegedly creating a prima facie case of obviousness against the claims before amendment. As noted above, claims 1-7, 11, 13, 14 and 31 have been amended to remove anilino at the 4-pyrimidine position.

New claims 37-39 allow anilino substituents containing a carboxyl group substitution. The Ceiplik compound does not contain a carboxyl group on the anilino ring, nor are the R³ and R⁴ groups in an isomeric or homolog relationship with the allowable substituents in the amended claims. The pending application is not prima facie obvious over this reference.

Ceiplik 6:

Claims 1-7, 11, 13, 14, and 31 stand rejected under 35 USC 103(a) over Cieplik, et al., Archiv der Pharm. (Weinheim, Germ.) (1997), 330(8), 237-241, which describes compositions of the following compound:

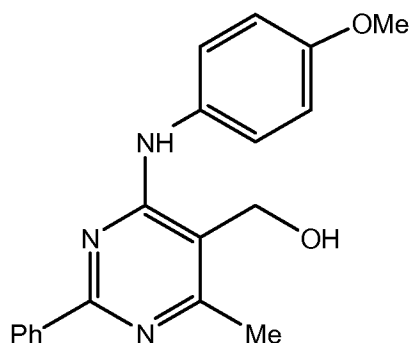


The reference was cited as allegedly creating a prima facie case of obviousness against the claims before amendment. As noted above, claims 1-7, 11, 13, 14 and 31 have been amended to remove anilino at the 4-pyrimidine position.

New claims 37-39 allow anilino substituents containing a carboxyl group substitution. The Ceiplik compound does not contain a carboxyl group substitution on the anilino ring, and the R³ and R⁴ groups are not in an isomeric or homolog relationship with the allowable substituents in the amended claims. The pending application is not obvious over this reference.

Ceiplik 7:

Claims 1-7, 11, 13, 14, and 31 stand rejected under 310UWC (a) over Cieplik, et al., Bollet. Chim. Farm. (1996), 135(8), 459-464, which describes compositions of the following compound:

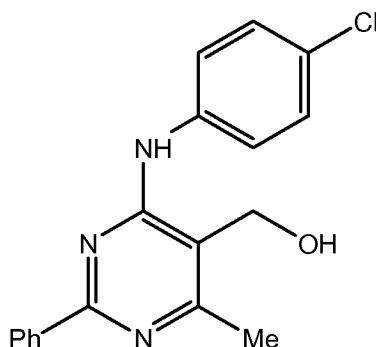


The reference was cited as allegedly creating a prima facie case of obviousness against the claims before amendment. Claims 1-7, 11, 13, 14 and 31 have been amended to remove anilino at the 4-pyrimidine position.

New claims 37-39 allow anilino substituents containing a carboxyl group substitution. The Ceiplik compound does not contain a carboxyl group on the anilino ring, nor are the R³ and R⁴ groups in either an isomeric or homolog relationship with the allowable substituents in the amended claims. The pending application is not obvious over this reference.

Machon 3:

Claims 1-7, 11, 13, 14, and 31 stand rejected under 35 USC 103(a) over Machon, et al., PL 164076, which describes compositions of the following compound:

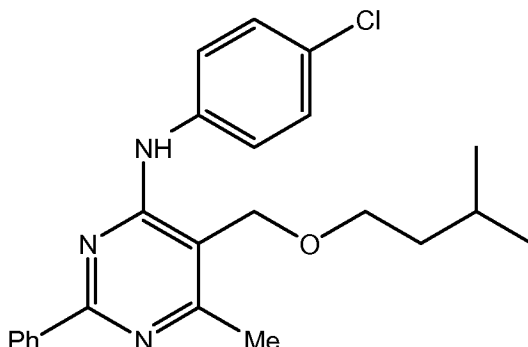


The reference was cited as allegedly creating a prima facie case of obviousness against the claims before amendment. As noted above, claims 1-7, 11, 13, 14 and 31 have been amended to remove anilino at the 4-pyrimidine position.

New claims 37-39 allow anilino substituents containing a carboxyl group substitution. The Machon compound does not contain a carboxyl group substitution on the anilino ring, nor are the R³ and R⁴ groups in either an isomeric or homolog relationship with the substituents in the amended claims. The pending application is not obvious over this reference.

Cieplik 8:

Claims 1-7, 11, 13, 14, and 31 stand rejected under 35 USC 103(a) over Cieplik, Farmaco (1995), 50(2), 131-6, which describes compositions of the following compound:

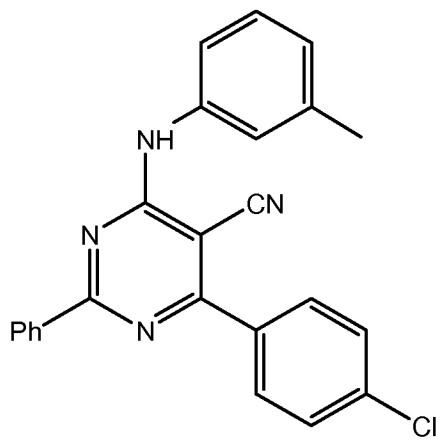


The reference was cited as allegedly creating a prima facie case of obviousness against the claims before amendment. As noted above, claims 1-7, 11, 13, 14 and 31 have been amended to remove anilino at the 4-pyrimidine position.

New claims 37-39 allow anilino substituents containing a carboxyl group substitution. The Cieplik compound does not contain a carboxyl group substitution on the anilino ring, nor are the R³ and R⁴ groups in an isomeric or homolog relationship with the allowable substituents in the amended claims. The pending application is not obvious over this reference.

Mincheva:

Claims 1-7, 11, 13, 14, and 31 stand rejected under 35 USC 103(a) over Mincheva, Doklady Bolgarskoi Akademii Nauk (1980), 33(7), 925-7, which describes compositions of compounds exemplified by the following compound:

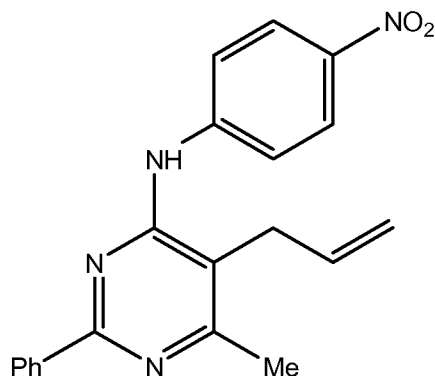


The reference was cited as allegedly creating a prima facie case of obviousness against the claims before amendment. As noted above, claims 1-7, 11, 13, 14 and 31 have been amended to remove anilino at the 4-pyrimidine position.

New claims 37-39 allow anilino substituents containing a carboxyl group substitution. The Mincheva compounds do not contain a carboxyl group substitution on the anilino ring, nor are the R³ and R⁴ groups in an isomeric or homolog relationship with the allowable substituents in the amended claims. The pending application is not obvious over this reference.

Nieland:

Claims 1-7, 11, 13, 14 and 31 stand rejected under 35 USC 103(a) over Nieland, WO 2004032716, which describes compositions of the following compound:

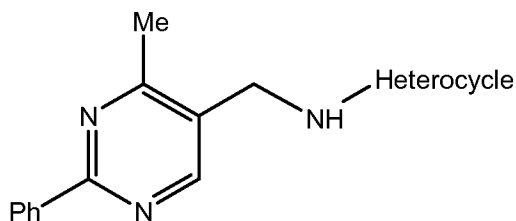


The reference was cited as allegedly creating a prima facie case of obviousness against the claims before amendment. Claims 1-7, 11, 13, 14 and 31 have been amended to remove anilino at the 4-pyrimidine position.

New claims 37-39 allow anilino substituents containing a carboxyl group substitution. The Nieland compound does not contain a carboxyl group substitution on the anilino ring, thus the pending application is not obvious over this reference.

Zhu:

Claims 1-7, 11, 13, 14 and 31 stand rejected under 35 USC 103(a) over Zhu, WO 005007143, which describes a compound having the following backbone structure:



The reference was cited as allegedly creating a prima facie case of obviousness against the claims before amendment. The Zhu compound does not contain the carboxyl group on an anilino, phenoxy, or thiophenoxy functional group, and the compound is neither an isomer nor homolog of compounds of the amended claims. The pending application is not obvious over this reference.

Objectionable Claims

Claims 1-11, 13, 14, and 31-36 were objected to as directed to both elected and non-elected subject matter. The amended claims recite only elected subject matter.

If it is believed that a teleconference will advance prosecution, the examiner is encouraged to contact the undersigned as indicated below.

Respectfully submitted,

Date: August 5, 2009

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